CROSPON™

EndoFLIP® EF-322 Catheter

Models: EF-322

EF-322N

Instructions for Use

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1. Introduction

The EndoFLIP® EF-322 Catheter is designed for use with the EndoFLIP® System, which displays estimates of the diameters at 16 points over a 16cm measurement length along the balloon. This catheter has an integrated pressure sensor for balloon pressure measurement.

Throughout this document the EF-322 will also describe the use of the EF-322N which is the same catheter but with a different packaging option.

1.1 How it works

The EF-322 Catheter acts as a Functional Lumen Imaging Probe (FLIP) that shows dynamic changes in the geometry of the measurement area in a real-time image.

The catheter connects to an EndoFLIP® System, which injects a conductive solution into the catheter balloon placed in the measurement area. The balloon contains an array of electrodes that measure voltage. The EndoFLIP® System uses these voltages to estimate the diameter at 16 points, 1cm apart, along the measurement area (see Figure 1).

Refer to the EndoFLIP® user manual for a further description of the system.

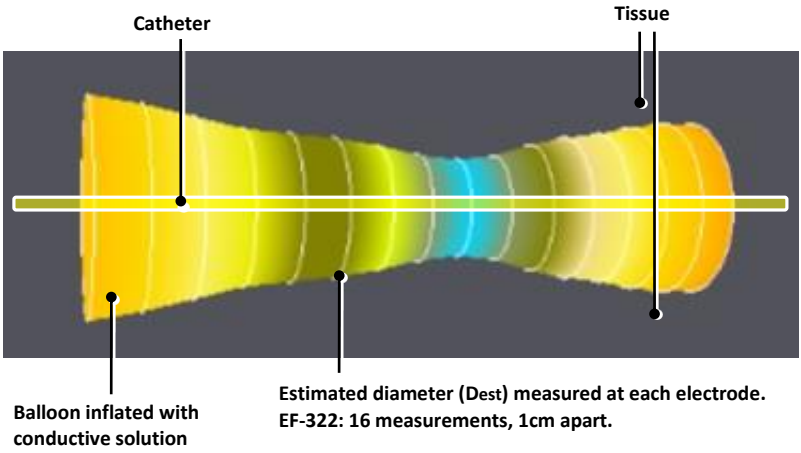

Figure 1: EndoFLIP® EF-322 Catheter

1.2 Intended Use

The following are the indications of use for the EndoFLIP® system and EF-322 catheter:

In the USA:

The EndoFLIP® System is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity.

Note: The EF-322 catheter is to be used only with the EndoFLIP® system.

Outside the USA:

The EndoFLIP® System is used in a clinical setting to obtain an estimation of the dimensions and balloon pressure within the alimentary canal.

1.3 Contraindications

- The EndoFLIP® System is contraindicated where endoscopy is contraindicated.
- Do not use the EndoFLIP® System on patients with actively-bleeding varices in the esophagus.
- The EF-322 catheter is not suitable for diameter measurements less than 5 mm.

1.4 Warnings

- ***Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization can: compromise the structural integrity of the device; impair performance accuracy due to residual fluid in the balloon and degrade the catheter markings.***
- ***Federal law (U.S.) restricts this catheter to sale by, or on the order of, a physician.***
- ***All catheter components are intended for single patient use only: do not attempt to reuse. Follow all applicable Federal and local regulations for disposal or recycling.***
- ***To ensure proper operation and to minimize the risk of patient injury, do not attempt to add or remove fluid from the supplied pre-filled syringes. Only use the pre-filled syringe supplied with the catheter.***

  Note: Different catheter part numbers are supplied with different solution concentrations.
- ***To avoid damaging the catheter and syringe, store away from sources of heat in specified environmental conditions (see Appendix A: Specifications).***
- ***Before using the EndoFLIP® System and catheter on a patient, allow the device to acclimate to conditions of use following transport or storage.***
- ***During operation, check that the amount of fluid in the syringe matches the amount shown onscreen, and verify that the syringe refills, as indicated when the plunger aligns***

with the arrow on the syringe (indicating that the balloon is empty) before carefully removing the catheter from the patient.

- ***Verify that there are no leaks in the catheter during the pre-use purge cycle described in the EndoFLIP® System user manual.***
- ***Replace the catheter if a Dest value remains consistently at a maximum or minimum compared to adjacent Dest values; this can indicate a faulty catheter.***
- ***Remove the catheter if the patient requires defibrillation.***
- ***For optimal pressure measurements, do not expose the balloon portion of the catheter to excessive light during the procedure.***
- ***Refer to the EndoFLIP® user manual for warnings relating to use of the EndoFLIP® System.***

2. Using the catheter

This section describes how to install and use the EndoFLIP® EF-322 Catheter.

2.1 Installing the catheter assembly

Warning: Before use, inspect the catheter assembly from end to end for breakage, occlusions, or debris. For single use devices, do not use if damage to the parts or packaging is evident, or if any portion of the package has been previously opened. Do not use any part after its expiration date or if the expiry date cannot be verified

1. Remove the catheter assembly from its packaging, remove the protective sheath from the balloon, and dispose of the sheath.
2. Place the balloon, tip first, into the EndoFLIP® pre-use checkout tube, which holds the balloon in a vertical position (see Figure 2).

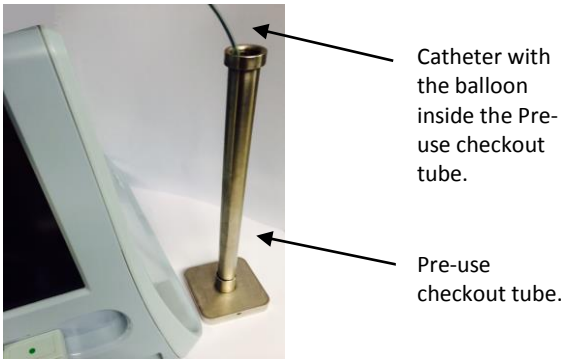

Figure 2: EndoFLIP® catheter in the pre-use check-out tube.

3. Prepare the catheter for use as described in the *EndoFLIP® System user manual*.

2.2 Placing the catheter: Esophageal Diameter measurements

Warning: Avoid using excessive force during insertion. Withdraw the catheter if resistance is too high.

1. Wipe down the catheter with an alcohol swab and apply lubrication to the catheter (if required).

2. Insert the catheter trans-orally under endoscopic visualization, or trans-nasally. Insert the catheter until:

   - Trans-oral: the 45-cm mark on the catheter aligns with the patient's teeth.
   - Trans-nasal: the 55-cm mark aligns with the patient's nose.

   If you feel any resistance during insertion, retract the catheter slightly, then carefully retry.

   Note: The markings on the catheter are referenced from the center of balloon.

3. Touch PRESSURE ZERO (if desired), then Inflate the balloon to 30 ml.
4. Adjust the balloon position as required to place the image of the GEJ near the bottom Dest on the EndoFLIP screen.
   Note: To enable distensibility and compliance displays, the balloon must contain at least 10ml and the balloon pressure must be at least 5 mmHg with the Dmin positioned on the five center Dests. Once the balloon has been positioned, a non-zero pressure may occur as a result of the positioning. You may zero the pressure displayed before starting balloon inflation.

5. When the procedure is finished, deflate the balloon fully, as indicated when the plunger aligns with the arrow on the syringe (See Fig. 4) and carefully remove the catheter from the patient.

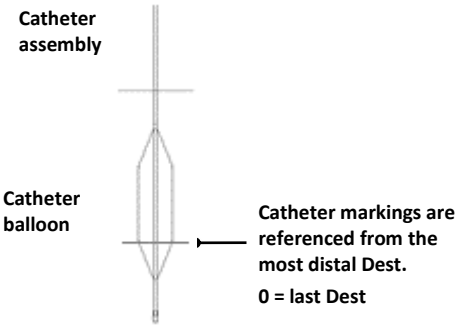

Figure 3: Zero Reference for catheter markings

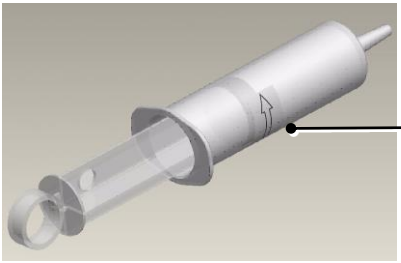

Figure 4: Syringe returned to original position

Warning: In the unlikely event that the EndoFLIP® System stops normal operation during a procedure, use the back panel on/off switch to turn the unit off, remove the syringe from the unit and retract the syringe plunger manually to withdraw any remaining fluid from the balloon catheter. The catheter can then be carefully removed from the patient.

2.3 Disconnecting the catheter

Once the procedure is complete and the balloon is deflated (as described in the *EndoFLIP® System user manual*), disconnect the catheter and syringe from the unit, and check the structural integrity of the catheter.

Warning: Single use device, follow all applicable Federal and local regulations for disposal or recycling of the syringe and catheter.

Appendix A: Specifications

Operating and storage conditions

Operating conditions

Temperature	20 to 40 °C
Humidity	15 to 95% relative humidity (non-condensing)
Atmospheric pressure	700 to 1060 hPa

Storage conditions

Temperature	0 to 25 °C
Humidity	10 to 95% relative humidity (non-condensing)
Atmospheric pressure	500 to 1060 hPa

Main label symbols

	Single-use device
	Storage temperature limits
	Use-by date
	Fragile
	Manufacturer

LOT	Batch code
REF	Part number
	Caution, consult accompanying documents
	Date of Manufacture
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.
Xn	Box contains quantity 'n' catheters

Catheter Specifications

Maximum Inflate Volume	72ml
Maximum Inflate Rate	60ml/min
Dest Measurement Range	5mm-22mm
Dest Measurement Accuracy	±1mm over measurement range.
Balloon Pressure Measurement Range	0mmHg to 150mmHg
Balloon Pressure Accuracy	±1mmHg over measurement range

Settable Balloon Pressure Alarm Limit	10mmHg to 150mmHg

Manufacturer information

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